JUN 3 0 2000

K001081

2 Summary and Certification

2.1 Premarket Notification 510(k) Summary

SUBSTANTIAL EQUIVALENCE:
Identification of predicate devices. model. and manufacturer:

Predicate functional device:	CardioDynamics BioZ.com System
Model:	Part # BZ-4010
Manufacturer:	CardioDynamics International Corporation
Predicate Device 510(k):	K974725
Reason for Submission:	Repackaging and repartitioning of functionality into separate PC and patient interface electronics. Internalization of SPO_2 electronics. Use of BioZ Portable user software.
Predicate software device:	CardioDynamics BioZ Portable System.
Model:	BZ-125
Manufacturer:	CardioDynamics International Corporation
Predicate Device 510(k):	K972320
Reason for Submission:	Repackaging and repartitioning of functionality into separate PC and patient interface electronics. Addition of internal blood pressure and SPO_2 electronics
Predicate package device:	BoMed CDDP
Model:	CDDP
Manufacturer:	BoMed Medical Manufacturing Ltd.
Predicate Device 510(k):	K890408
Reason for Submission:	Addition of internal blood pressure and SPO_2 electronics/

The BioZ.pc Hemodynamic Monitor is substantially equivalent to its predicate devices, the BioZ.com System currently marketed by CardioDynamics International Corporation, the BioZ Portable, and the BoMed CDDP System. The justification for this substantial equivalence determination is presented below.

The BioZ.com Hemodynamic Monitor is substantially equivalent to the BioZ.com System in terms of design, intended use and principle of operation. The BioZ.pc Hemodynamic Monitor simply re-packages and re-partitions the electronics of the product for the convenience of users who wish to use an external 586 (Pentium) PC for data display and storage rather than the embedded 386 PC that is an internal part of the BioZ.com product package. The BioZ.pc has nearly identical user software (at both the source code and executable code levels) to another predicate device, the BioZ Portable System. BoMed Medical Manufacturing Ltd. the predecessor company to CardioDynamics International Corporation marketed a similarly-packaged device in 1992, (with a separate PC and Patient Interface Module) to which we also claim substantial equivalence.

The PC software which provides the user interface for the BioZ.pc system is loaded onto the PC using a software installation kit, identical to the method used for the predicate devices, the BioZ.com and the

BioZ Portable. Both devices store the user software on the hard drive of the PC component of the system. Both products use an identical software integrity check when the monitoring software is first activated, to insure that no corruption has occurred of any of the operating software used by the device.

CardioDynamics International Corporation has labeled the BioZ.pc software clearly on the installation kit diskette, the installation instructions in the kit, and the user manual instructions for use only with particular models of notebook PC's which have been previously validated by CardioDynamics for use with the BioZ.pc product. The validation protocol used by CardioDynamics in included in this submission in Appendix E2. The labeling for the user software limiting the use to only validated PC models is included in Appendix A.

Both the BioZ.com and the BioZ.pc systems are portable in design and for use in the hospital, outpatient and clinical settings. The intended use of the BioZ.pc is to noninvasively measure a patient's hemodynamic parameters using Impedance Cardiography (ICG). Monitoring is accomplished by attaching 8 electrodes to the patient (two on each side of the neck and thorax), injecting a minimal current through the upper electrodes, and reading the returning voltage waveform from the inner electrodes.

The BioZ.com Hemodynamic Monitor utilizes CardioDynamics' proprietary DSP electronic circuitry and software incorporating formulas and algorithms to calculate the various hemodynamic parameters. The user inputs patient parameters into the user software, including patient gender, body frame size, height, weight, age and blood pressure. The Monitor then utilizes these parameters and measures the ICG signals to determine the hemodynamic properties of that particular patient. The patient interface circuit board (which provides all data acquisition, isolation, and defib protection), patient cable, and ICG electrodes are identical to those provided with the BioZ.com product.

All three predicate devices (the BioZ.com System, the BioZ Portable System, and the BoMed CDDP) along with the new BioZ.pc Hemodynamic Monitor are IBM PC-based products, which differ only in partitioning and packaging. All utilize the DOS operating system, either alone or within Windows 98.

CardioDynamics International Corporation will provide previously-validated models of notebook PC's to customers as part of BioZ.pc system purchases, labeled with the system as model number BZ-501. Each PC provided will be fully tested with its BioZ.pc device prior to shipment and its outer shipping carton will be labeled as shown in Appendix A. Since notebook PC's have a very short product life, provisions have been made to validate replacement PC's over the life of the product. The protocol for this validation is included as Appended E2.

Substantial equivalence is shown in the following table (on the next page):

Attribute	BioZ.pc (New)	BioZ.com (Predicate)	BioZ Portable (Predicate)	BoMed CDDP (Predicate)
Pt. Interface Circuitry, connector, cable, and electrodes	CDIC P/N 1014801 Same as BioZ.com. All accessories same as BioZ.com	CDIC P/N 1014801 Same as BioZ.pc. Same connector, cable, and electrode as BioZ.pc	CDIC P/N 16-300 1996 vintage circuitry. Same connector, cable, and electrode as BioZ.pc	1986 vintage circuitry, connector and cable. Same electrode as BioZ.pc
Pt. Circuitry Package	Internal to BioZ.pc Instrument	Internal to BioZ.com Instrument	Internal to BioZ Instrument	Internal to CDDP Instrument
CPU	Intel 586 or equivalent PC	Intel 386EX PC	Intel 486 PC	Intel 386 or Equivalent PC
CPU Packaging	External PC	Internal to BioZ.com Instrument	Internal to BioZ Instrument	External PC
PC Operating System	DOS within Windows® 98	DOS 6.22	DOS 6.22	DOS 3.1
PC Software Installation Kit	Manufactured and supplied per CDIC Manufacturing Procedure 02-121	Manufactured and supplied per CDIC Manufacturing Procedure 02-121	Manufactured and supplied per CDIC Manufacturing Procedure 02-121	N/A Predates CDIC's quality system
User Interface software	BioZ ver 1.52 (based on CDDP)	BioZ.com V2.26	BioZ 1.52 based on CDDP	CDDP
User Display	External PC VGA Screen	BioZ.com internal ¼ VGA screen	Internal VGA Screen	External PC VGA Screen
Blood Pressure Electronics	Internal to BioZ.pc Instrument	Internal to instrument	Externally connected to PC via serial data cable	Externally connected to PC via serial data cable
Pulse Oximeter Electronics	Internal to patient interface box	Externally connected to instrument via serial data cable	Externally connected to instrument via serial data cable	Externally connected to PC via serial data cable
DSP Packaging	Internal to BioZ.pc Instrument	Internal to BioZ.com Instrument	Internal to BioZ Portable Instrument	N/A No DSP
DSP Firmware	CDIC ZMARC Ver 2.15	CDIC ZMARC Ver 2.15	CDIC ZMARC Ver1.09x	N/A No DSP.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2000

Mr. Dennis G. Hepp
Chief Technology Officer
CardioDynamics International Corp.
6175 Nancy Ridge Drive, Suite 300
San Diego, CA 92121

Re: K001081
Trade Name: BioZ.PC Hemodynamic Monitor Model BZ-500/BZ-501
Regulatory Class: II
Product Code: 74 DSB
Dated: March 29,2000
Received: April 5, 2000

Dear Mr. Hepp:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597,
or at its internet address
"http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known):

Device Name: BioZ.pc Hemodynamic Monitor

Indications for Use:

The BioZ.pc Hemodynamic Monitor is intended to monitor and display a patient's hemodynamic parameters when used in conjunction with the appropriate BioZ.pc User Interface Software and a validated IBM-compatible Personal Computer. These parameters include:

ECG	Pre-Ejection Period	Systolic Time Ratio
Cardiac Output	Heart Rate	End diastolic Index
Thoracic Fluid Content	Acceleration Index	Cardiac Index
Left Vent. Ejection Time	Index of Contractility	SPO_2
End Diastolic Volume	Mean Blood Pressure	Stroke Volume
Systemic Vascular Resistance	Systolic Blood Pressure	Left Cardiac Work
Diastolic Blood Pressure		

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The_Counter Use _____

(PER 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Melkerson
Fred Lacy for JXW

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001081